# ATTACHMENT 31

**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF CALIFORNIA**

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| **IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION** | **Lead Case No. 3:21-cv-03825-VC** |
| **THIS DOCUMENT RELATES TO:**<br><br>**ALL CASES** | |

# EXPERT REPORT OF CHRISTY FOREMAN, MBE

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# Table of Contents

developing a separate definition for the new term "remanufacturer," and that this was supported by comments that were received on the proposed rule.

74. Trautman suggests that the supposed "lack of clarity" related to FDA's definitions of "refurbishing" or "servicing" is of import in this case.[50] However, where a party engages in the activities listed in the definition of "remanufacturer," there can be no doubt that the party is a remanufacturer and is subject to the associated regulatory requirements.

## B. Opinion 2 – EndoWrist instruments were cleared by FDA as limited use devices, and efforts to remove or extend the usage limitation by companies other than the original equipment manufacturer (OEM) constitute remanufacturing activities.[51]

### 1. FDA cleared EndoWrist instruments as limited use devices.

75. The usage limitation is an essential safety and performance specification for the EndoWrist instruments. Intuitive engaged in extensive life and performance testing, which was submitted to FDA, to provide FDA a reasonable assurance of the safety and the effectiveness of the device.

76. The device descriptions in both K965001 and K990144, the earliest 510(k) submissions for the da Vinci Surgical System and its instruments, state that the instruments are "resposable" and "limited use."[52] The fact that the "indications for use" in the 510(k) summaries do not specifically state that EndoWrist instruments are subject to limited use

[50] Trautman Report §§ V, VI; ¶¶ 46, 76.

[51] Efforts to remove or extend the usage limitation by the OEM, Intuitive, constitute manufacturing and are also subject to premarket requirements.

[52] Intuitive-00691660; Intuitive-00692314.

makes no difference, as the usage limitations were clearly indicated in the device descriptions and elsewhere in the 510(k) submission.

77. In order to understand FDA's clearance of EndoWrist instruments as limited use devices, it is helpful to look at certain premarket submissions for EndoWrist instruments.

a) K990144

78. The original 510(k) for Intuitive's EndoWrist family of instruments as well as subsequent 510(k)s demonstrate that the instruments were cleared by FDA as limited use devices.

79. On January 18, 1999, Intuitive submitted a 510(k) for additional instruments to be used with the Intuitive Surgical Endoscopic Instrument Control System (Model IS1000), including scissors, scalpels, forceps, clip applier, electrocautery and accessories, pick-ups and needle drivers/holder.[53] The trade name listed for the instruments in this 510(k) was Intuitive Surgical™ Instruments/Accessories: "Resposable" (limited reuse) Endoscopic Instruments.

80. In its Substantial Equivalence Comparison/Rationale, Intuitive explained: "Intuitive Surgical has worked hard to reduce risks associated with the use of the Endoscopic Instrument Control System to an absolute minimum. This has been done through extensive failure modes effects and criticality analysis (FMECA) . . . and extensive fail-safe and redundant design assuring no uncontrolled instrument movement. This fail-safe design has been verified

[53] Intuitive-00692310.

and validated through both in vitro and in vivo testing including more than 170 clinical procedures to date."[54]

81. Intuitive provided the instrument and accessory physical specifications to FDA, and explained that "Tool ID electronics . . . provide electronic recognition of the tool, and store number of uses remaining in memory."[55]

82. Furthermore, "[t]he system electronics is responsible for performing all telepresence control functions and video processing functions of a sophisticated electro-mechanical system in a surgical environment. Additionally, and of at least equal importance, it is responsible for detecting system faults and taking such protective actions as necessary so as to ensure both patient and operating room staff safety under all conceivable failure conditions."[56]

83. FDA solicited additional information from Intuitive on the limited use nature of its instruments as part of the 510(k) review. Among FDA's requests was a "summary of your validation of the reuse instructions for the 'resposables'" and "a mechanism for assuring that single use instruments such as scalpels and electrocautery will not be confused with 'resposable' and will not be reused."[57]

84. Intuitive explained in Section 3.8 of the Device Description, "Summary of Pre-Clinical Studies," the testing done to ensure mechanical reliability. Intuitive explained, "*In vitro* component and sub-system cycle life and durability testing has been performed. This work

[54] Intuitive-00692321, at -2324-25.

[55] Intuitive-00692451, at -2454.

[56] Intuitive-00692433, at -2436.

[57] Intuitive-00692185, at -2205-06.

has included mechanical arms and instruments and has demonstrated reliability consistent with product labeling and use recommendations. Instruments are programmed to "expire" and not be useable after a predetermined amount of usage in order to assure reliable operation and the absence of "wear out."[58]

85. On July 11, 2000, FDA cleared the instruments, writing, "Based upon the product technical information, intended use, and performance information provided in the pre-market notification, the Intuitive Surgical Endoscopic Instrument Control System has been shown to be substantially equivalent to currently marketed predicate devices."[59]

b) K013416

86. On October 12, 2001, Intuitive submitted another 510(k) for certain EndoWrist instruments, including endoscopic forceps, graspers, needle drivers, scissors, scalpels (K013416). In the 510(k) Summary, Intuitive explained: "The subject device(s) consist of a family of endoscopic instruments with either grasping or cutting and effectors to be used with the Intuitive Surgical da Vinci Endoscopic Instrument Control System. . . . The instruments are re-usable (for a limited number of uses), are provided non-sterile, and must be cleaned and sterilized before use (pre-vacuum autoclave). . . . The instruments are provided for a limited number of uses to ensure reliability and consistent performance, and have non-volatile 'add-only' memory that the Instrument Control System decrements after each use."[60]

[58] Intuitive-00692611, at -2634.

[59] Intuitive-00691203, at -1204.

[60] Intuitive-00515501, at -5508-09.

87. Intuitive also provided testing data in this submission. It explained that standard bench testing data was performed for each of the subject EndoWrists as part of standard verification and validation testing conducted prior to commercial introduction.[61] The testing included a life cycle test: "Perform range of motion cycles on each wrist axis based on expected range of motion during surgical procedures to determine that the cables don't derail or fray, that the pulley turns, and that the wrist unit functions correctly after the test."[62] Intuitive also noted that there were no FDA performance standards for these devices, but the EndoWrists were "designed, manufactured, and tested in accordance with voluntary safety standards."[63]

88. On December 12, 2001, the FDA sent a deficiency letter to Intuitive regarding the K013416 filing, requesting that Intuitive address the identified deficiencies related to usage limits, biocompatibility, and Ultrasonic Shears.[64] Specifically, the FDA wrote, "On page 12, you state that the instruments are re-usable for a limited number of uses. The instruments are programmed for a limited number of uses to ensure reliability and consistent performance, and have non volatile 'add-only' memory that the system decrements after each use. Please specify the number of uses for each instrument and describe how the numbers were determined. Please provide data to support the claim."[65]

[61] Ibid. at -5519.

[62] Ibid. at -5521.

[63] Ibid. at -5527.

[64] Intuitive-00481165.

[65] Ibid. at -1166.

89. Intuitive explained to FDA that the "number of uses is determined by testing instruments under conditions that replicate actual clinical use, and cycling these instruments for wear expected during the specified number of procedures. . . . Performance measurements are made periodically (e.g., at the end of each cycle or set of cycles) to confirm that the instrument is still performing as intended, and the life testing is continued until failure or a specified number of cycles are successfully completed."[66]

90. On January 10, 2002, FDA granted clearance for the K013416 510(k).[67]

c) K131861

91. On June 19, 2013, Intuitive submitted a 510(k) for its Model IS4000 Da Vinci Xi surgical system and EndoWrist instruments (K131861).

92. As with the earlier submissions, Intuitive submitted performance testing data, including life testing data, demonstrating that the EndoWrist instruments had been validated for a certain number of uses.[68]

93. On March 28, 2014, FDA granted clearance for the K131861 510(k) submission.[69]

d) K170644

94. This 510(k) applies to multiple instruments and accessories that have been cleared through a number of 510(k) Premarket Notifications, including the 8mm Si

[66] Ibid. at -1168.

[67] Intuitive-00481176.

[68] Intuitive-00493612.

[69] Intuitive-00861667.

Monopolar Curved Scissors. It concerns the Reprocessing Instructions provided to users for reprocessing of instruments and accessories intended for multiple usage.

95. This device was also listed as a predicate device for the K210478 510(k), discussed below in Section IV.B.1(h), in which Iconocare sought clearance for an additional 10 uses beyond what was originally cleared by FDA for the 8mm Si Monopolar Curved Scissors.

96. This submission validated the devices for the labeled number of reprocessing cycles for the instruments establishing that the device meets performance specifications after a representative number of uses.

e) K180033

97. This 510(k) was submitted by Intuitive Surgical for the EndoWrist 8mm Monopolar Curved Scissors instrument used with the Intuitive Surgical IS2000 da Vinci S Surgical System or IS3000 da Vinci Si Surgical System for cutting, cauterizing, coagulation, manipulating and blunt dissection of tissue.

98. This device was listed as one of the predicate devices for K210478. Specifically, Iconocare submitted the K210478 510(k) to seek clearance for an additional 10 uses beyond what was cleared in this 510(k) for the Si 8mm Monopolar Curved Scissors.

f) K214095

99. In December 2021, Intuitive submitted a 510(k) to FDA for "extended lives" on certain instruments intended for use with the X and Xi da Vinci Surgical Systems.[70]

[70] Intuitive-02054168.

100. The submission included testing data demonstrating that the X/Xi EndoWrist instruments could be used for a greater number of lives than the number for which they were originally cleared.[71]

101. On August 15, 2022 FDA notified Intuitive that clearance was granted for K214095.[72]

g) K143619

102. I am aware of two manufacturers other than Intuitive who have submitted 510(k)s seeking clearance to extend the usage limits on EndoWrist instruments: Rebotix, LLC and Iconocare Health.

103. Rebotix submitted K143619 on December 18, 2014 for "re-manufactured EndoWrists."[73] According to Rebotix:

> Re-manufactured EndoWrists are intended to be used in the same manner as their OEM counterparts. The conditions of use and operating principle are identical. The re-manufactured EndoWrists described above can only be used with the da Vinci S and da Vinci Si Systems, in accordance with the indication of these host systems.
>
> Specifications and allowable tolerances have been established for each of the remanufactured EndoWrists, in order to ensure that they maintain OEM-equivalent safety and performance throughout the intended extended use cycles.[74]

[71] K214095 510(k) Summary, available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K214095.pdf. This 510(k) is discussed in further detail in Section IV.D.2.

[72] Ibid.

[73] REBOTIX170421, at -0424.

[74] REBOTIX131433 at -1436.